SCIENCE ADVISORY BOARD

LE CONSEIL CONSULTATIF DES SCIENCES

MEETING REPORT

RAPPORT DE LA RÉUNION

October 8-9, 1998

les 8 et 9 octobre 1998

Health Canada
October 1998

Santé Canada
octobre 1998

Note: Contents of the Meeting Report are a reflection of the discussions of the October 8-9, 1998 Science Advisory Board Meeting. The points contained in this document are those of the Science Advisory Board and do not necessarily reflect the views of Health Canada and its employees./ Le contenu du présent rapport est le reflet des discussions de la réunion du Conseil consultatif des sciences tenue les 8 et 9 octobre 1998. Les points de vue qui y sont exprimés sont ceux du Conseil consultatif des sciences et ne reflètent pas nécessairement les points de vue de Santé Canada et de ses employés.

Meeting Notes[1]

October 8, 1998

- The Vice-Chair opened the meeting and welcomed Members to Winnipeg.

- Current activities in Government which may impact on the Health Protection Programme were raised, for example, the status of the federal Biotechnology initiative.

  As a representative from the Health Portfolio, Dr. Yves Morin provided a brief overview of the progress of the Council of Science and Technology Advisors. He noted the establishment of two working groups, the first to discuss *The Role of the Federal Government in Performing Science and Technology*, the second *Scientific Advice in Government Decision Making.*

  The Branch discussed its efforts to enhance visibility and credibility in view of the ongoing public debate related to the its activities and to clarify the diversity of opinions being expressed.

  Members encouraged the Branch to put forth messages of balance and reality in response to the controversies. The Board indicated that it should reflect on its role, if any -- this issue should be part of the next meeting s agenda.

- Discussion of the **Report of the July, 1998 Science Advisory Board meeting:**

  Members agreed with the draft Report, with some revisions.

- **Health Protection Program -- Status on Transition.** Ian Shugart, Visiting Assistant Deputy Minister, Health Protection Branch, provided a status report on the Transition initiative, in particular the vision and mission of the Programme and the Science Platform. Discussion of the Food Program Development initiative was deferred to the following morning, in view of the time given to the first two items and the Board s visit of the Winnipeg facility.

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[1]Text shown in bold italic represents recommendations, conclusions, follow-up activities and decisions of the Board.

The purpose of the discussion was to seek guidance on developments in these initiatives. This was also an opportunity to provide initial results of the consultation sessions on Legislative Renewal/Risk Management and Public Involvement.

Members commented on the importance of a strong **vision** for the programme, especially in meeting the challenges of the 21st century. Members discussed a few concepts which warrant further consideration. These included:

- The value of a clear vision statement in supporting leadership, building cohesiveness, exploring new directions and addressing the public perception of eroding authority in health protection.

- The development of models for an organization which functions in keeping with its fundamental mandate and evolves with challenging environments.

- The importance of understanding terms such as health and health protection in the development of a Vision statement, in particular in terms of the potential to clearly identify and build partnerships to achieve that vision.

- The relevance of the historical evolution of health protection programmes, the Branch s central role, nationally, and how it relates in the larger context of global forces. Visual representation of such concepts may be useful.

Members noted that a renewed vision statement would be an important blueprint or point of reference for the Board s work in assessing the Branch s directions and achievements.

Ian Shugart addressed developments on the Branch s **Science** platform (ref Appendix C), and referred to the latest Draft of *The Way Forward - More Effective Health Protection Laboratory Science and Testing*. Members discussion centered on related concepts, including:

- There are many concepts and models for a Science Manager . At one level, this Manager could focus on basic management functions such as establishing consistent standards, ensuring scientific integrity and cooperation, systematic external peer review and priority setting/resource allocation exercises. On another level, this person could be a chief high level advocate for science in the programme, internally and externally to

the department -- an Ambassador at large . As these models represent very distinct roles, it would be wise to consider whether the two can be integrated into one position.

- Credibility, independence and currency are key features for the performance of science in the Branch. The management of the science platform can take several forms -- from a fully integrated major virtual organization to matrix organizations which function along parallel lines of priority setting, resource allocation, etc. Integration of processes of systematic peer review for expanding and existing research is fundamental to the Branch s science programs.

- The definition and enhancement of accountability and its relevance to the precautionary principle should be clearly outlined. Its strategic thrust for the Branch s science platform should be to establish trust and build synergy with global platforms.

Members supported the Branch s direction in its Science platform and encouraged a move forward to establish leadership models in keeping with the Branch s mandate and vision.

- **National Blueprint for Surveillance - progress to date** -- David Mowat, Director, Surveillance Transition (ref Appendix D). Dr. Michael Shannon, Director General, Laboratory Centre for Disease Control also participated. The presentation outlined the goals, objectives and directions of the F/P/T Integration Design Team and its linkages to the work of the Advisory Committee on Population Health. The presentation also outlined progress to date on the National Health Surveillance System, a component of the Canadian Health Infostructure. The purpose of the discussion was to obtain guidance on the principles and directions proposed.

  Members discussion centered on related concepts, some of which should be further developed, including:

  - Surveillance, to achieve its full potential as a fundamental tool for health protection, must be pro-active and future-looking. This includes gathering / mining of key information; developing and maintaining an expert analytical capacity; periodic review and testing to verify capability; and, performance evaluation to enhance capacity.

- There are currently several existing surveillance tools in Canada and globally -- a major challenge will be to bring together the expertise , to integrate as it relates to basic information and to communicate the trends and interventions as they relate to health protection.

- Surveillance technology is evolving rapidly -- innovative developments, pilot projects and operationalizing efforts are ongoing. Technology provides tools for surveillance -- the current initiatives strive to ensure that the tools are being developed in accordance with principles of a true pan-Canadian surveillance partnership.

- As technology advances, one of the standard problems is the variance of terms being utilized -- common language is a basic premise for comprehensiveness and effectiveness of national surveillance. For example, neonatal mortality is interpreted differently within Canada and internationally.

- For Canadians, an immediate challenge is privacy of personal information -- current technology is rapidly evolving and must be used to assure the security of personal information. The major issue will be accountability, in a broader sense. Canadians will expect to access information and understand where public funds are being directed; that they will be able to obtain knowledge on health trends and specific disease states; and, that Health Canada, as the national health authority, will have certified this information.

- As health information becomes widely accessible and understandable, the real impacts of health determinants such as cultural and socio-economic status will become clearer. This could lead to renewed discussions of ethical issues, for example, should health initiatives focus on individualistic needs or on the global public good?

Members supported the directions taken by the Programme in its surveillance integration work with the Provinces and Territories. For Canadians, meaningful knowledge must be accessible in relation to individuals and in relation to disease trends and risk factors overall.

The Board re-iterated earlier statements that the real power of information is that it generates knowledge -- Canadians and public health authorities can access this knowledge in making their health-related decisions.

- ***Winnipeg Laboratory Tour and Presentations***, -- a tour of the facility and presentations by Dr. Finlay, CFIA and Dr. Wendy Johnson, Director, Bureau of Microbiology, LCDC. (Appendix E and F respectively)

  Members discussion touched on several issues, particularly inquiries about work undertaken in the facility and efforts to enhance collaborative initiatives with other scientific activities in Winnipeg and globally, including:

  - While CFIA research focuses on foreign animal diseases, collaborative initiatives with HPB research should be fully explored, for example, prion research.

  - Collaborative initiatives are being explored for the HPB component, in conjunction with the University of Manitoba. Some restrictions applicable to HPB may need to be reconsidered, for example joint research which would result in commercial benefits to the collaborator are currently not permitted.

  - Although 70 positions in the HPB component have been filled, there are currently 50 empty positions. High calibre scientists will help draw interest. Innovative recruitment strategies are critical to reach full potential and capitalize on the unique opportunity of the facility for human/ animal health research. Adequate and secure funding will be key to doing the job right .

  In the Board s view, given the facility s proximity to Winnipeg s research community and the growing potential for international collaborative initiatives, the laboratory should be able to produce cutting-edge research. The Board requested that it be advised of the facility s progress .

- ***Health Protection Branch -- Safe, Nutritious Food Program***, an update by Ian Shugart, to outline current developments. Robert Clarke, Director, Program Development, Transition also participated.

  The Board confirmed: the Food Programme requires a clear accountability framework to regain public confidence; the primacy of health and safety in decision making; the need to stabilize resources in the science capacity; the relevance of legislative renewal in supporting Branch s critical role; and, progress in defining roles and accountabilities of federal agencies who share the

mandate of safe and nutritious food (for example, HPB, CFIA and PMRA).

The Board generally endorsed the directions taken by the Programme and advised the Minister of Health of the following:

The Science Advisory Board has during its 1998 meetings been briefed upon and made its contributions to the re-development of HPB s food program. The Board agrees that this re-development is not only necessary at this time but urgent.

At the meeting of October 8-9, the Board agreed to recommend as follows:

1. ***The program s approach as described in the Safe and Nutritious Food Program is sound and deserves appropriate financial support.***
2. ***This integrated program cannot be delivered by any other agency or entity. Responsibility and means are wholly within the purview of Health Canada.***
3. ***The SAB feels the HPB should satisfy the Minister on the question of whether the results of the program can be satisfactorily delivered.***
4. ***Similarly, we feel HPB should specifically satisfy the Minister that, associated with the program, will be measures to address the development of public confidence in HPB s work to fully meet its responsibility regarding the quality and safety of the Canadian food supply.***

Further, the Board stresses that in this program as in all other scientific activities of HPB, the fundamental principles of peer review and regular external assessment must be scrupulously observed. Steps regarding peer reviewed external assessment should be taken immediately. Implementing the food program will require putting in place the necessary modalities, and the Board is confident that this can be done by HPB in a timely and orderly fashion.

- **The Drug Review Process** -- a presentation by Dann Michols, Director General of the Therapeutic Products Programme and Marta Caris, Acting Director of the Bureau of Pharmaceutical Assessment (ref Appendix G). The presentation was at the request of the Board, in view of the current controversy related to this program activity. The Board noted its interest in receiving advice from other stakeholders in future.

  The presentation provided an overview of the management of the drug review process by the Therapeutic Products Programme. Issues, challenges and achievements were presented, within a context of a global regulatory

environment. The purpose of the discussion was to respond to inquiries from the Board about the issues raised and to initiate a discussion within the Board leading to guidance which could be the basis of ultimate recommendations to the Minister.

Board discussion centered on related concepts and some important considerations. These included:

- Differences and similarities between the Canadian drug review process and its achievements in relation to other countries (such as the United States, the European Community, Australia, the United Kingdom) need to be pursued more aggressively. The Programme should consider best practices and analogies which would support its initiatives to increase efficiency in the process.

- It is vital that the Programme and its scientific personnel integrate developments with regards to international consensus on the definition of priority review , the criteria for priority review and on the uniform application of these criteria.

- Strengthened priority-setting and resource allocation, within a framework which includes systematic external peer review, is key to reaching full potential of the Programme.

- The health of Canadians is the criterion for decision making. The Programme must address several key issues in the public domain, including:

  - perceptions related to cost recovery and the Programme s relationship with industry as clients ;
  - the perception of conflict of interest, and the debate in relation to scientific integrity being influenced by recovered costs;
  - the time required for drug reviews, especially those for critical health care situations -- addressing new or emerging special cases;
  - international harmonization, main directions must be consistent with Canadian law and values; and,
  - priority setting must be rigorous and be based on well established and well communicated criteria.

Members commented that it would be wise to investigate priority considerations if a product may offer more benefits to the Canadian people

(while not representing a considerable economic profit).

- Members inquired on the transparency of the drug review process, rights to proprietary privacy and the implications of the Access to Information regulation. The Programme explained its current mechanisms, including External Advisory Panels (all stakeholders, including consumers and industry), Expert Advisory Groups (scientific advisors only) and consultation sessions, for example this summer s public consultations related to HIV/AIDS therapies. The Programme re-iterated that the final decision making authority rests within -- however, it is investigating approaches to address the challenges of transparency and public involvement in decision making.

Members commented favourably on many of the directions taken by the Therapeutic Products Programme in meeting the challenges of the Drug Review Process. They noted that the Programme should increase its public communications efforts.

They re-iterated their intention to continue discussions on this subject, to obtain the views of other stakeholders and to consider, at their next meeting, a strategy to obtain this advice.

APPENDICES TO MEETING REPORT OF October 8-9, 1998

Appendix A - Agenda for October 8-9, 1998
Appendix B - Participants to October 8-9, 1998 meeting.
Appendix C - Health Protection Program - Science Core
Appendix D - National Blueprint for Surveillance
Appendix E - Winnipeg Laboratory Tour
Appendix F - Winnipeg Laboratory Tour
Appendix G - The Drug Review Process

Appendix A

AGENDA
SCIENCE ADVISORY BOARD
October 8-9, 1998
Sheraton Winnipeg Hotel
161 Donald Street
Winnipeg, Manitoba

Day 1

8:30 Coffee/Tea/Juice in Anteroom of Meeting room.

9:00 **Welcome** and remarks by the Chair

9:05 **Discussion of the Report of the July, 1998 SAB meeting** **All**
- this discussion is intended to lead to a final version of the Report, for subsequent release.

9:45 **Standing item:** **Ian Shugart**
Current activities in Government which impact on the Health Protection Programme.

10:00 **Health Protection Program -- status report on Transition** **I Shugart**
A status report on the Transition initiative, including the Vision/Mission paper, Food Program Development and Science Core. Guidance will be sought on developments in these three initiatives, which were discussed at the last meeting. This will also be an opportunity to provide initial results of the consultation sessions on Legislative Renewal/Risk Management and Public Involvement.

- Plenary discussion (to answer questions and to identify issues which may have arisen from the presentation) All

12:00 **Lunch**

1:00 **The National Blueprint for surveillance**- progress to date **David Mowat**
The presentation will outline the goals, objectives and directions of the F/P/T Integration Design Team and its linkages to the work of the Advisory Committee on Population Health. The presentation will outline progress to date on the National Health Surveillance System, a component of the Canadian Health Infostructure. The purpose of the discussion is to obtain guidance on the principles and directions proposed.

- Plenary discussion (to answer questions and to identify issues which may have arisen from the presentation) All

3:00	Health Break	
3:15	**Tour of the Winnipeg facility** *(Representatives of Winnipeg s research community have been invited to join the Board)*	
5:00	**Presentation by Winnipeg Laboratory site Managers** -- an overview of the operational and science plans for the facility. There will be a presentation on opportunities for scientific collaboration.	
6:00	Adjournment	
7:00	Dinner, at the Dubrovnik, 390 Assiniboine, Winnipeg, Manitoba	

Day 2

7:30	Coffee/Tea/Juice in Anteroom of Meeting room.	
8:00[1]	**The Drug Review Process -- challenges and achievements.** At the request of the Board, the presentation will provide an overview of the management of the drug review process by the Therapeutic Products Programme. Issues, challenges and achievements will be presented, within a context of a global regulatory environment.	**Dann Michols**
	• Plenary discussion (to answer questions and to identify issues which may have arisen from the presentation)	All
11:00	**WORKING LUNCH** and **Open Discussion,** allowing for further discussion, if desired of the Drug Review Process or on collaboration opportunities for the Winnipeg Laboratories. An opportunity for Members to review progress to date on the Transition initiative and the work of the Science Advisory Board.	
1:00	**Business arising from last meetings and activities of the Board**	**All**
1:30	**Closing remarks and Adjournment**	**Roberta Bondar**

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[1]A few Members travel schedules conflict with a later adjournment, hence the early start.

Appendix B

Participants to the Science Advisory Board meeting of October 8-9, 1998

Vice-Chair:

Dr. Yves Morin
1280, Pantaléon-Pelletier
Sillery (Québec)
G1T 2H4

Members:

Mr. Doug Elliott
Elliott & Kim
Barristers/Solicitors
National Bank Building
304 - 150 York Street
Toronto, Ontario
M5H 3S5

Mrs. Jean M. Jones
Chair - Health Council
Consumer Association of Canada
19 Brentwood Drive
Dundas, Ontario
L9H 3N2

Dr. Mohamed Karmali
Division of Microbiology
The Hospital for Sick Children
555 University Avenue
Toronto, Ontario
M5G 1X8

Dr. Nuala P. Kenny
Bioethics Education and Research
Dalhousie University
5849 University Avenue
Halifax, Nova Scotia
B3H 4H7

Dr. Wilbert Keon
University of Ottawa Heart Institute
Ottawa Civic Hospital
1053 Carling Avenue
Ottawa, Ontario
K1Y 4E9
(Day 2 only)

Dr. John S. Millar (2nd day only)
Vice President
Canadian Institute for Health
Information
377 Dalhousie Street, Suite 200
Ottawa, Ontario K1N 9N8

Mr. Leslie Millin
c/o Elsie Wollaston
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Dr. Karen Semchuk
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S7N 0W8

Health Canada Members

Mr. David Dodge
Deputy Minister
Health Canada
Brooke Claxton Bldg., Room 1526-A
Tunney's Pasture
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Dr. Joseph Z. Losos
Assistant Deputy Minister
Health Protection Branch
Health Canada
HPB Building, P.L. 0701-A1
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Ottawa, Ontario
K1A 0L2

Other Health Canada contacts

Mr. Ian Shugart
Visiting Assistant Deputy Minister
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HPB Building, P.L. 0701-B1
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Ottawa, Ontario
K1A 0L2

THE SCIENCE CORE

- What **is** the Science Core?
- **Principles** that must be adhered to when considering potential models
- What sort of **models**?
- The Science Manager - concepts and selection

THE SCIENCE CORE

- Principles applicable to the Science Core:
  - Ensure consistent and good laboratory management;
  - Develop and maintain a precise and clearly focused mandate and priorities;
    - What is our niche? [vide infra]
  - Ensure that the Branch has the capacity to deal with new threats to the public health;
  - Ensure efficient use of science dollars while maintaining scientific excellence

THE SCIENCE CORE

- Principles applicable to the Science Core: (Contd.)
  - Ensure that laboratories deliver the science that meets program needs;
  - Ensure that the laboratories are flexible in their approach and are able to adapt to continual change;
  - Encourage development of and support an outward-looking, co-operative scientific culture within the laboratories;
  - Actively encourage interaction between HPB laboratory scientists with colleagues in governments and health organizations around the world;

THE SCIENCE CORE

- Types of laboratory activities:
  - IN HOUSE:
    - Routine analysis and testing not undertaken by third parties
    - Response to emergencies
    - Current needs and obligations
    - Anticipatory research (prioritized!)
  - OUT OF HOUSE
    - Contractual
  - PARTNERSHIPS
    - Cooperative ventures

THE SCIENCE CORE

- What is our niche?
  - OECD Paper "*The changing role of Government Research Laboratories*" (1989) suggested the following answers to the question of <u>why</u> governments need to conduct research:
    - Where confidentiality is required
    - When intellectual independence is necessary in the face of industrial/commercial interests
    - Provide continuity, particularly in regard to the quality of research
    - The need to have an adequate level of expertise (in relation to subcontracting)
    - close contact between those who conduct and those who utilize the research

THE SCIENCE CORE

- What is our niche? **(Contd)**

Contract to validate, update and define in more detail the Health Protection Program's niche

- Active participation of Directorates
- Final Report presented to Science Committee/SAB

THE SCIENCE CORE

- First Steps to the integration of Health Protection Program's laboratory function
  - Need to set up infrastructure to serve all of the Health Protection Program's laboratory-science needs
  - Not all areas of activity may merit integration
  - A stepwise and considered approach to change
  - Examples:
    - Enterics/zoonotics approach
    - Potential for integration of Toxicology function between EHD and Food Directorate

THE SCIENCE CORE

- Enterics/Zoonotics/Food capacity
  - Integration of microbiological research between HAL (Guelph), Bureau of Microbiology (Winnipeg) and Bureau of Microbiological Hazards (Food)
  - Integrate planning/Review/Delivery
  - Links program (client) needs for delivery
  - External advisor/consultant to assist process

THE SCIENCE CORE

- Infrastructure
  - We need to work towards a common planning and resource allocation process based on Health Protection Program's priorities.
  - The Science Core should provide support to all Branch laboratories in areas such as:
    - prioritization and resource allocation
    - HR strategies including future competencies, promotions
    - peer review
    - partnerships and alliances
    - patents
    - conflict of interest
    - accreditation
  - By ensuring that we operate in a consistent manner across all HPB laboratories, we would become a more attractive partner

An Integrated National Surveillance Network for Canada

Update on Activities

to the Health Canada Science Advisory Board

October 8/9, 1998

An Integrated National Surveillance Network

- Policy Drivers
- Needs
- Requirements
- Expected Outcomes
- Process
- Progress to Date

An Integrated National Surveillance Network

Policy Drivers

HPB Surveillance Transition

Canada

National Network Policy Drivers

Recommendations from:

- ***IHAC*** **(Information Highway Advisory Committee);**

- ***CANARIE*** **(Canadian Network for the Advancement of Research, Industry and Education);**

- ***The National Forum on Health;***

- ***F/P/T Working Group on Roles and Responsibilities***

all call, in some way for:

National Network Policy Drivers, cont'd

... a strengthened national health information network featuring co-operation among all levels of government, fostered by federal government co-ordination which addresses gaps in current capacity, integrated across the health sector and with an emphasis on evidence-based decision making.

An Integrated National Surveillance Network

Needs

HPB Surveillance Transition

Canada

National Network Needs:

- Better use of existing data sources
- Better interpretation of data
- Improved quality
- Timely information
- Broader scope of health surveillance
- Information which is easier to use

all in support of... evidence-based decision-making

An Integrated National Surveillance Network

Requirements

HPB Surveillance Transition

Canada

National Network Requirements:

- A well-defined and accepted governance framework, providing adequate and continued leadership.
- A strong emphasis on the development of skilled human resources.
- A high degree of validity, relevance and timeliness combined with simplicity of use.
- A priority setting process.
- A high degree of internal integration and integration to the larger health sector infrastructure.

National Network Requirements (cont'd)

- Comprehensive in scope but with the flexibility for rapid response.
- A strong communications capacity.
- A resource for surveillance expertise, methods development and national coordination.
- A strong link with standards-setting organizations (e.g. CIHI, CSA).
- A secure system in which relevant ethical issues have been addressed and where the privacy and confidentiality of individuals is preserved to the greatest extent practicable.

An Integrated National Surveillance Network

Expected Outcomes of the Design Team Process

HPB Surveillance Transition

Canada

Expected Outcomes [I]

- Recommendations for improving the:
  - integration
  - scope
  - governance

of an Integrated National Surveillance Network for Canada

Expected Outcomes [2]

- involving:
  - all orders of government
  - health practitioners
  - non-government organizations
  - academics
  - private sector

Expected Outcomes [3]

a functional description of an integrated national surveillance network which will include .....

- **roles and responsibilities of surveillance partners**
- **governance**
- **planning & priority setting**
- **core surveillance business processes and their data needs**
- **surveillance infrastructure gaps**

and...

Expected Outcomes [4]

- Recommendations to improve the collaborative priority setting and system planning to maximize each component to the benefit of the system as a whole
- To provide an assessment and recommendations on how to move the present system toward a truly integrated surveillance network

The National Centre for Foreign Animal Disease (NCFAD)

Government of Canada / Gouvernement du Canada

Canada

Federal Laboratories
Winnipeg, Manitoba

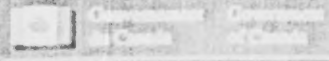
Canada

Facility Provides a UniqueTool

- Level 4 biocontainment
- Designed for both human and animal disease
- Flexibility

Facility Philosophy

- Biosecurity:
  - no disease agent escapes the building
- Safety
  - absolutely safe environment in which to work
  - "Box within a box" principle



Size and Scope

- Gross area = 29,300 square meters
  - Health Canada - 70 %
  - NCFAD - 30 %
- NCFAD - 85 % of the biocontainment space

Quick Facts

- The Federal Laboratories complex is the first facility in the world to combine laboratories for both human and animal disease research.

Quick Facts

- The facility contains Canada's first Level 4 laboratory, providing the capability to work safely with the most serious human and animal diseases.

CANADIAN FOOD INSPECTION AGENCY

MANDATE

- To enhance the effectiveness and efficiency of federal food inspection and related services for food and animal and plant health.

NATIONAL CENTRE FOR FOREIGN ANIMAL DISEASE

VISION

- Our centre will be the preferred international source of knowledge and skill on the diagnosis, management and training of foreign animal disease.

NATIONAL CENTRE FOR FOREIGN ANIMAL DISEASE

MANDATE

- To support the promotion of international trade and the protection of the national animal health status through the prevention and control of foreign animal disease.

New Concepts

- Stand-alone capability in Winnipeg, Manitoba
- Areas of program involvement
- Policy and epidemiology group
- Interdepartmental cooperative management of the complex
- Synergism of teams

Areas of Program Involvement

Facility is equipped to handle:

- Foreign animal diseases
- Zoonotic diseases
  (transmitted from animals to people)
- Emerging diseases

What We Do

- Diagnostic testing for foreign animal diseases (no other source in Canada)
- Provision of scientific advice
- Technology development
- Scientific reference for Standardization/Quality Assurance (QA)
- Production of unique diagnostic reagents
- Policy and strategy development
- Training

What We Do

Training:

- Foreign animal disease recognition
- Technology application
- Outbreak management
- Postgraduate

Bringing this together

- A bigger and better pie
- New concepts and new dimensions for national animal health program in Canada
- Unique facility - international recognition
- Serving the Canadian agricultural industry and the Canadian public better

An Integrated National Surveillance Network

Process

HPB Surveillance Transition

Canada

Surveillance Design Team Mandates

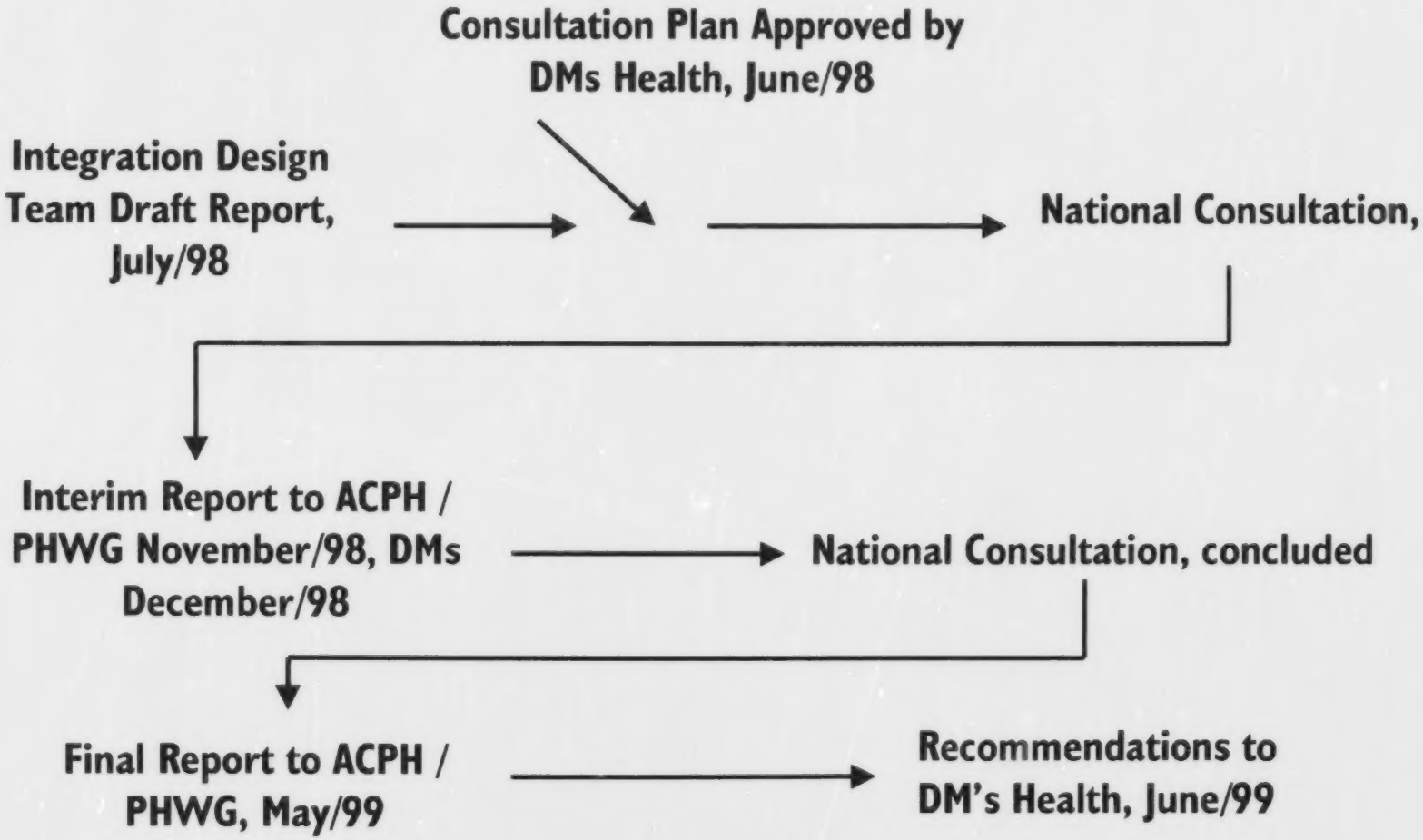
Surveillance Integration Design Team

- roles and responsibilities
- national priority setting process
- include mechanisms for non F/P/T contribution

Functional Schematic Design Team

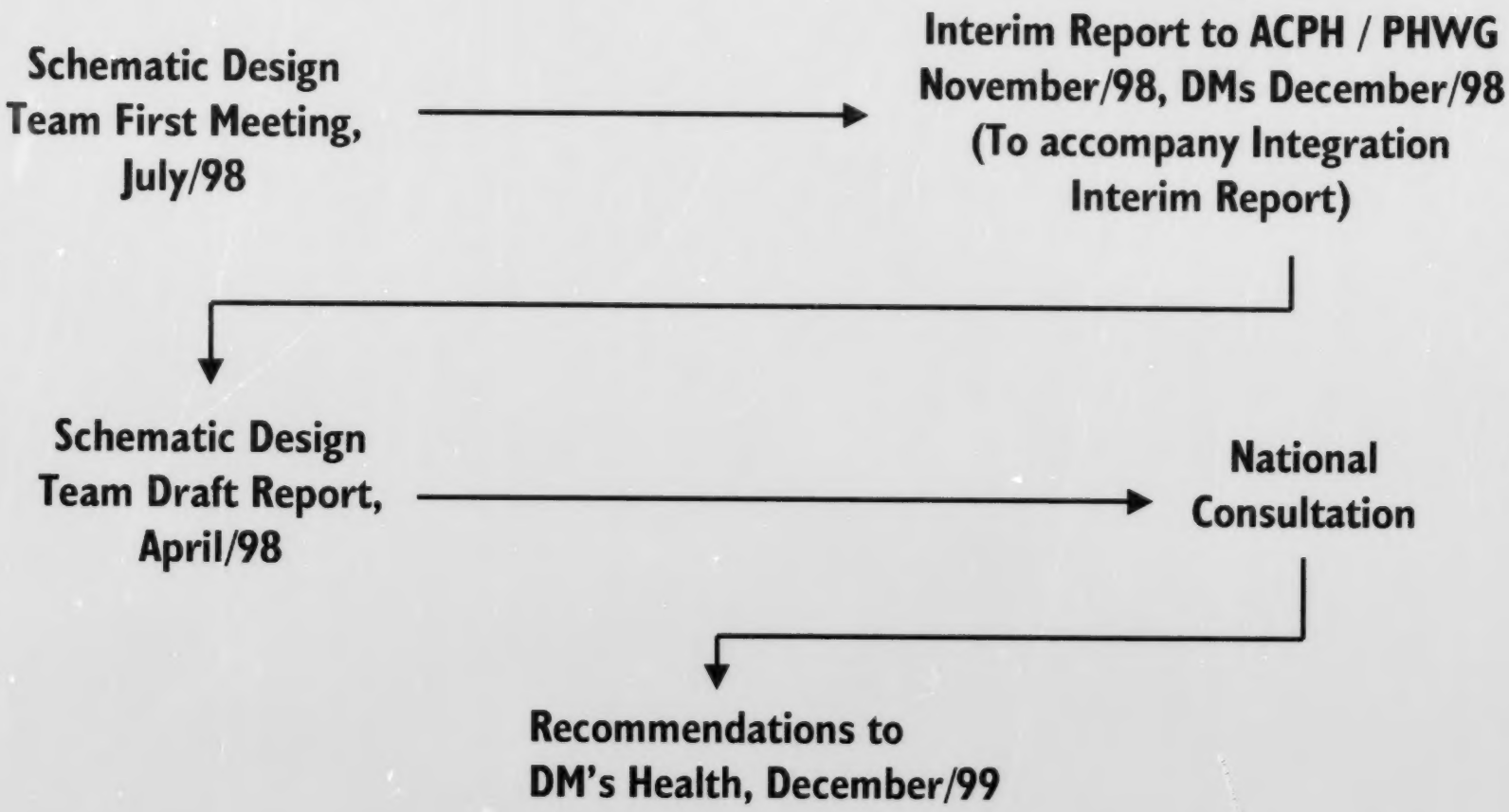
- surveillance business processes
- evaluation mechanisms

Surveillance Transition Process: Integration Design


Consultation Plan Approved by DMs Health, June/98
Integration Design Team Draft Report, July/98
National Consultation,
Interim Report to ACPH / PHWG November/98, DMs December/98
National Consultation, concluded
Final Report to ACPH / PHWG, May/99
Recommendations to DM's Health, June/99

Canada

Surveillance Transition Process: Functional Schematic Design


Schematic Design Team First Meeting, July/98
Interim Report to ACPH / PHWG November/98, DMs December/98 (To accompany Integration Interim Report)
Schematic Design Team Draft Report, April/98
National Consultation
Recommendations to DM's Health, December/99

Canada

An Integrated National Surveillance Network

Progress to Date

HPB Surveillance Transition

Canada

PROGRESS TO DATE

- Integration design team has developed a final Draft Report, ready for national consultation which addresses:
  - Rationale of a National Health Surveillance Network
  - Core Elements (Accountability Framework, National Goals and Objectives, National Protocols, Electronic Information Infrastructure, National and International Linkages, Human Resource Requirements, Funding)
  - Functions of a National Surveillance Network
  - Identification of Issues and Recommendations

PROGRESS TO DATE, cont'd

- The Office of Surveillance Transition has developed, with the Integration Team, a Draft Consultation plan which was approved by DMs of Health in June/98. This plan has been reviewed and scoped for available resources. Implementation will begin in October/98.
- The Functional Schematic Design Team has met twice and has produced a framework for its Final Report and a detailed work plan to produce the Report.

Operationalizing the F/P/T Framework:

The National Health Surveillance Info-structure (NHSI)

HPB Surveillance Transition

Canada

WHAT IS THE NHSI ?

The NHSI is an integral component of the Canadian Health Info-structure -

comprising a suite of integrated surveillance pilots which:

- ✓... are Internet based
- ✓ ... build national health intelligence infrastructure
- ✓ ... complement provincial, regional & local activities
- ✓... employ a common IM approach

Why the NHSI?

- Technology only one component of system

- Need to demonstrate feasibility of Internet-based infrastructure

- Lengthy process

- Demonstrates feasibility of approach; does not commit network to priorities or disease/program issues

Canada

WHAT WILL THE NHSI DO?

- Make Better Use of the Health Information We Already Have

- Provide an Early Warning System for Disease Outbreaks and Newly Emerging Hazards

- Build a Better Understanding of Your Community's Health and Safety

NHSS IMPACT?

- Leveraging existing information bases and networks
- Broadening the scope of health surveillance
- An integrated approach to health information
- Web based national and international surveillance networks
- New governance models
- Building sustainable public health networks
- State of the art technology
- Policy and program decision support

Making Better Use of the Health Information We Already Have

. . Provide the Canadian Health System the Information it Needs When it Needs it -

- Spatial Public Health Information Exchange ("SPHINX")
- Therapeutic Products Surveillance System ("TPSS")
- Poison Control Information Exchange ("PRODNet")
- Public Health Information Dbase("PHIDB")

An Early Warning System for Disease Outbreaks and Newly Emerging Hazards

. . . In Canada - "CIPHS"

(Canadian Integrated Public Health System)

. . . Around the World - "GPHIN"

(Global Public Health Intelligence Network)

Build a Better Understanding of Your Community's Health and Safety

. . . Where Public Health Meets the People - LoPHID"

(Local Public Health Infrastructure Development)

HPB Surveillance Transition

Canada

Why the NHSI?

- Technology only one component of system

- Need to demonstrate feasibility of Internet-based infrastructure

- Lengthy process

- Demonstrates feasibility of approach; does not commit network to priorities or disease/program issues

Canada

WHAT WILL THE NHSI DO?

- Make Better Use of the Health Information We Already Have

- Provide an Early Warning System for Disease Outbreaks and Newly Emerging Hazards

- Build a Better Understanding of Your Community's Health and Safety

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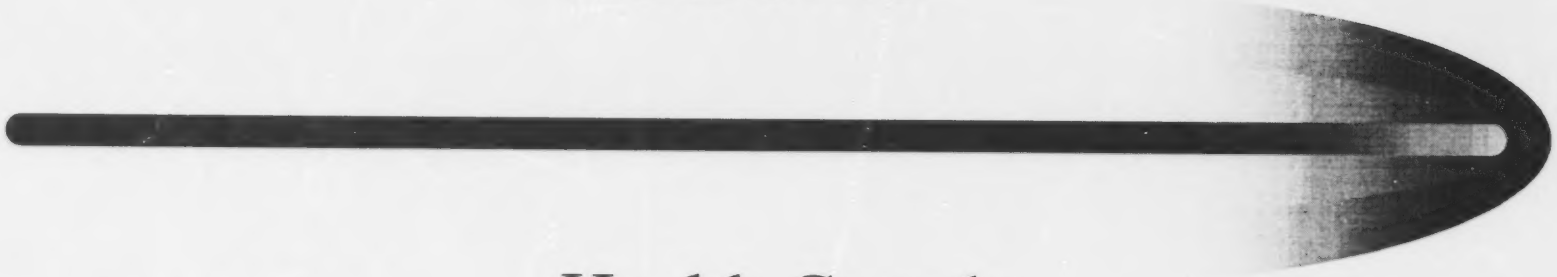
HPB Surveillance Transition

Canada

Appendix F

Bienvenue
Welcome



Health Canada

Science Advisory Board

8 October 1998

LCDC MISSION

To be the National Laboratory Centre for the:

Identification,
Investigation,
Control and
Prevention of human disease

CORE LABORATORY ACTIVITIES

- Reference Services
- Surveillance
- Outbreak Investigation
- Research and Development
- Quality Assurance & Proficiency Testing
- Training and Technology Transfer

IMPACTS

- Reduce Morbidity and Mortality
- Hazard Identification & Risk Assessment
- Produce and Provide Diagnostic Reagents
- Detect and Identify Emerging Pathogens
- Evaluate Vaccine Efficacy
- Recommend Control & Prevention Strategies

CORE SERVICES

- Media
- DNA Core Facility "*LCDC RADAR ROOM*"
- Biosafety
- Environmental Safety
- Small Animal Facility
- Continuing Education Teaching Laboratory
- Electron Microscopy at BSL2
- Fermentation Facility at BSL3

DISEASES & INFECTIONS BEING STUDIED

- Enteric and Foodborne
- Sexually Transmitted
- Respiratory
- Zoonotic
- Bloodborne
- Central Nervous System
- Oncogenic Viruses

ADVISORY COMMITTEES

COMMITTEE	*ACRONYM*
Technical Advisory Committee	TAC
Advisory Committee on Epidemiology	ACE
Canadian External Quality Assessment	CEQA
Advisory Group for Antibiotic Resistance	AGAR

National Reference Centres (External to LCDC Winnipeg)

- Enteroviruses (Halifax, NS)
- Epstein Barr Virus (Montreal, PQ)
- Human Mycotic Diseases (Edmonton, AB)
- Parasitology (Serology) (Vancouver, BC)
- Streptococcus (Edmonton, AB)
- Rabies (Toronto, ON)
- TPI (Toronto, ON)
- Yersinia (Toronto, ON)

Provincial and Other Laboratory Networks

- Provincial Labs
- Regional HC Labs
- Hospital Labs
  - CHEC (Canadian Hospital Epidemiology Committee)
- Other Federal Departments
- National Proficiency Testing Programs
  - CMPT, LPTP, LSPQ
- International Networks and Reference Labs
  - WHO, PAHO, PHLS, CDC

VISION:

New & Unique Capabilities

- BSL4 Programme (> 15 Viruses)
  - Ebola
  - Lassa Fever
  - Marburg
  - Variola
  - Monkeypox
  - Herpes B

VISION:

Enhanced Viral Diagnostics

- BSL3 (> 30 Viruses & Rickettsia)
  - Hantavirus
  - Sin nombre virus
  - Rocky Mountain Spotted Fever
  - Herpes
  - Powassan
  - St. Louis Encephalitis
  - Western Equine Encephalitis

VISION:
New Partnerships - Manitoba

- University of Manitoba
  - Medical School
  - Fort Garry Campus
- St. Boniface Research Center
- University of Winnipeg
- Red River Technical College
- Local Biotechnology Industry
- NRC Biodiagnostics Institute

VISION:
New Partnerships - National

- CFIA and Foreign Animal Disease Program
- Medical Research Council (PDFs, Scholars)
- Other Granting Agencies
- Networks of Centres of Excellence (CBDN)
- University COOP Programmes
  - Biosafety specialization
  - Fermentation technology
- National Biotechnology Strategy

VISION:
New Partnerships - International

- BSL4 Laboratories in other countries
- Prion Reference Laboratories in Europe, UK and US
- Regulatory Agencies
  - Agriculture
  - Food and Drug
  - Environmental Protection
  - Quarantine and Travel

VISION:
Enhanced Bacterial Diagnostics

- BSL3
  - Tuberculosis
  - Anthrax
  - Brucellosis
  - Tularensis
  - Plague
  - Glanders
  - Melioidosis

VISION: Challenges

- Human Resources
  - Recruitment of qualified scientists
  - Professional Development
- Impediments to Science & Technology interactions with the private sector
  - Conflict of interest guidelines
- Rationalization of Level II Biosafety Practices

The Drug Review Process in Canada

Presentation to HC Science Advisory Board

Dann M. Michols

October 1998

Contents of Presentation

1. **Strategic Guidelines For Programme**
2. **Submission Review Process**
3. **Performance Measurement**
4. **Relevant Policy/Regulatory Initiatives**
5. **Role of Consultation/Communication**
6. **Cost Recovery Initiative**
7. **Barriers to Enhanced Performance**

1. Strategic Guidelines for Programme

- ★ Mission
- ★ Vision
- ★ Strategic Objectives
- ★ Regulatory Philosophy
- ★ Scope of Products Regulated
- ★ Business Lines

Programme Mission - Protection of Canadians

To ensure that the drugs, medical devices, and other therapeutic products available in Canada are safe, effective, and of high quality and that narcotic and restricted substances are controlled in an effective and efficient manner.

Programme Vision - National & International

- To be recognized as the national authority for the benefit/risk management of products intended for therapeutic use in Canada;
- To be respected around the world as one of the most effective agencies in drug and medical device regulation; and
- To be an effective national and international partner in the management of controlled drugs and substances.

Programme Objectives Reworked as Result of Consultation

- To ensure Canadians: have timely access to safe, effective, high quality products; are not put at undue risk by the use of the products available on the Canadian market; and receive appropriate information about the benefits and risks of those products.
- To ensure the regulatory system in Canada: is innovative, responsive to its environment, and conducive to the timely introduction of effective therapeutic products into the Canadian market; is developed with the full involvement of clients, stakeholders, and the public; and provides national and international leadership in therapeutic product regulation.

Programme Philosophy
Updated as well

- Intervene no more than is required to accomplish mission, but certainly no less.

- Base regulatory activity on principles of:
  1. benefit/risk management.
  2. shared responsibility among industry, researchers, health professionals, the Provinces, patients, their interest groups, and the public.
  3. "precaution" as recommended by Justice Krever.

Programme Workload
Scope of Products Regulated

- Pharmaceuticals (Prescription & OTC)
- Biologicals (Blood, Vaccines, T/O, Biotherapies)
- Radiopharmaceuticals
- Natural Health Products/Nutriceuticals
- Medical Devices
- Disinfectants/Sanitizers
- Narcotic, Controlled, & Restricted Substances

Programme Planning
Business Lines

- Pre-Market Authority
- Product Licensing
- Establishment Licensing
- Post-Market Surveillance
- Compliance/Enforcement
- Drug Analysis Services
- Controlled Substances Surveillance
- Programme Support

2. Drug Submission Review: How the System Works

1. **The Drug Development Process**
2. **Access to Drugs In Canada**
3. **Clinical Trials Regulatory Reform**
4. **Pre-Market Review Process:**
   - ► **Submission Types**
   - ► **Management of Drug Submission Review Policy**
   - ► **Structure in Review Bureaux**
   - ► **International Comparisons**
5. **Augmenting In-House Expertise**
6. **And If The Sponsor Disagrees?**
7. **The Impact of Patent Status**

Access to Drugs in Canada: Regulatory Framework In Transition

- **Food & Drugs Act/Regulations**
  1. **Clinical Trials/Compassionate Access**
  2. **Marketing Authorization**
     - ✓ **Product Licensing**
     - ✓ **Establishment Licensing**
  3. **Special Access Programme**
  4. **Personal Import**

- **Controlled Drugs & Substances Act**

Regulatory Framework in Transition: Current Approach

- ➤ Lower Risk
  - Class Product Monograph
  - Labelling Standards
  - Traditional Herbal References
  - ➤ Drug Identification Number (DIN)

- ➤ Higher Risk
  - New Drug Submission
  - Product Monograph
  - ➤ Notice of Compliance

- ➤ On the Market unless Safety/Quality Questioned

Regulatory Framework in Transition: Proposed Approach

- ➤ PRE MARKET REVIEW
  - Four Categories of Risk
  - Evidence according to Risk Presented
  - ➤ Product License

- ➤ POST MARKET MONITORING
  - Monitoring according to Risk Presented
  - Three Categories of Risk
  - ➤ Renewed License

Clinical Trials Regulatory Reform: Results Will Benefit Canadian R&D

- ► Current Regulatory Framework
  - ► All Phases must be approved
  - ► 60 day default provision
- ► Process Reform
  - ► Review dependent on level of risk
  - ► Pre-IND Consultations
  - ► Electronic Submissions
  - ► Introduce performance targets
- ► Change in Policy and Regulations

Clinical Trials Regulatory Reform: Process Reflects TPP Approach

- 1993 - Renewal Project - workshop
- Phase 1 changes (C&M, Notify new sites)
- Phase 2 changes (Pre-IND, IND unit)
- 1995 - Review & Approval Policy (evaluation in 1 year)
- 1996 - Stakeholders Workshop, WG
- 1997 - Final Report (risk-based, notify Phase 1, electronic submission, templates, summary-based)
- REB concerns
- May - Workshop (MRC, NCEHR, +)
- July - Report for comments
- Dec. - Analysis > Action Plan for change (e.g. perf targets >30 days)

Pre-Market Review Process: Submission/DecisionTypes

- Submissions
  - New Drug Submission (NDS)
    - Priority, NAS, Other
  - Abbreviated New Drug Submission (ANDS)
  - Supplementary New Drug Submission (SNDS)
  - Notifiable Change (NC)
  - Drug Identification Number (DIN) Application
- Decision Documents
  - Screening Deficiency
  - Clarifax (does not stop clock)
  - Notice of Deficiency (NOD)
  - Notice of Compliance (NOC)
  - Notice of Compliance with Conditions (NOC/C)
  - Notice of Non-Compliance (NON)
  - NON or NOD/Withdrawal (NON/W, NOD/W)

Pre-Market Review Process:
Management of Drug Submissions Policy

- ► Pre-NDS Meeting
- ► Industry Submission
  - – Registering
  - – Screening
  - – Review
  - – Decision
- ► Industry Response (if necessary)
  - – Supplementary Screening
  - – Supplementary Review
  - – Final Decision
- ■ Industry Appeal (if needed)

- ► Policy - 5th edition
- ► Priority Status
- ► Queue - 1st in/1st out
- ► NOC/C - policy not regulation

Pre-Market Review Process:

Structure of Review Bureaux - Pharmaceuticals

Pharmaceutical Assessment

- ► Submission Management
- ► Clinical Unit 1
  - ► AIDS & Viral Diseases
  - ► Central Nervous System
  - ► Cardiovascular Diseases
  - ► Immunology & Infectious Diseases
- ► Clinical Unit 2
  - ► Endocrinology & Metabolic Diseases
  - ► Gastroenterology Hematology & Oncology
  - ► Drug Evaluation
- ► Pharmaceutical Quality
- ► Bioequivalence Evaluation
- ► Product Information
- ► Natural Health Products

Elements to note:

- ► Screening step
- ► Clinical Unit managers new
- ► Manage business of review
  - ► Human Resources
  - ► External Review Contracts
  - ► Review committees
  - ► Consistency of Decisions
  - ► Research Initiatives
- ► Capacity to balance resources

Pre-Market Review Process:
Structure of Review Bureaux - Biologics

Biologics & Radiopharmaceuticals

- ► Management of Submissions Review
- ► Vaccines
- ► Blood & Tissues
  - ► Blood System
  - ► Blood Products
  - ► Tissues & Organs
  - ► Xenographs
- ► Biotherapeutics
- ► Radiopharmaceuticals
- ► Research/Laboratory Services

Elements to Note:

- ► Vaccines, blood, tissues, xenografts are different.
- ► In-house capacity for methodology and standards development, laboratory testing, and research.
- ► Capacity for pre-marketing inspections as process review is essential concern.
- ► Close interaction between laboratory and review scientists.

Augmenting In-House Expertise
Role of Consultants and EACs

- Consultants
  - Could be used in all aspects of review
  - Vetted for Conflict of Interest
- Expert Advisory Committees
  - 6 EACs and counting
  - Core and Ad Hoc members
  - Questions of science and medicine
  - Advisory not decision-making
  - Chair determines accessibility to EAC
  - Agendas/Notes on Web-site

And If the Sponsor Disagrees?
A New Process for Appeals

- 2 Levels
  - Pertains to any TPP review decision
  - Based on original data
  - Not cost recovered
- 1st level appeal
  - Director of Review Bureau
  - Review process, issues
- 2nd level appeal
  - Reviewed by Office of Science
  - Appeal Committee - usually 3 members
  - Chair drawn from EAC, if possible

The Impact of Patent Status
The Patent Linkage Regulations

- Bill C-91 - Amendments to Patent Act
  - Linked NOC to Patent Status
  - Rationale: pre-working, stock-piling
- Process
  - Patent Register
  - Notice of Allegation with Submission
  - Patent-Holder Decision
  - TPP Review of Submission
  - NOC held pending:
    - Court decision
    - Patent expiry

3. Performance Measurement
How Well the System Works

1. **Concept**
2. **Performance Targets**
3. **Selected Performance Actuals**
4. **Performance Reporting**

Concept of Measurement
Something New to Programme

$$P = f(Q, Eff, R)$$

where P is performance (time/quality)

Q is quality of dossier

Eff is efficiency of process

R is resources ($/skills)

Performance Targets

- Attempt to benchmark TPP activity
  - against own performance
  - against "peer" performance
- Purpose: Facilitate management of process
  - Queue - keyed to filing date
  - Targets not deadlines
  - Averages not absolutes
  - No relationship to fees paid
- History - DSTS, 1995, 1996

Performance Reporting

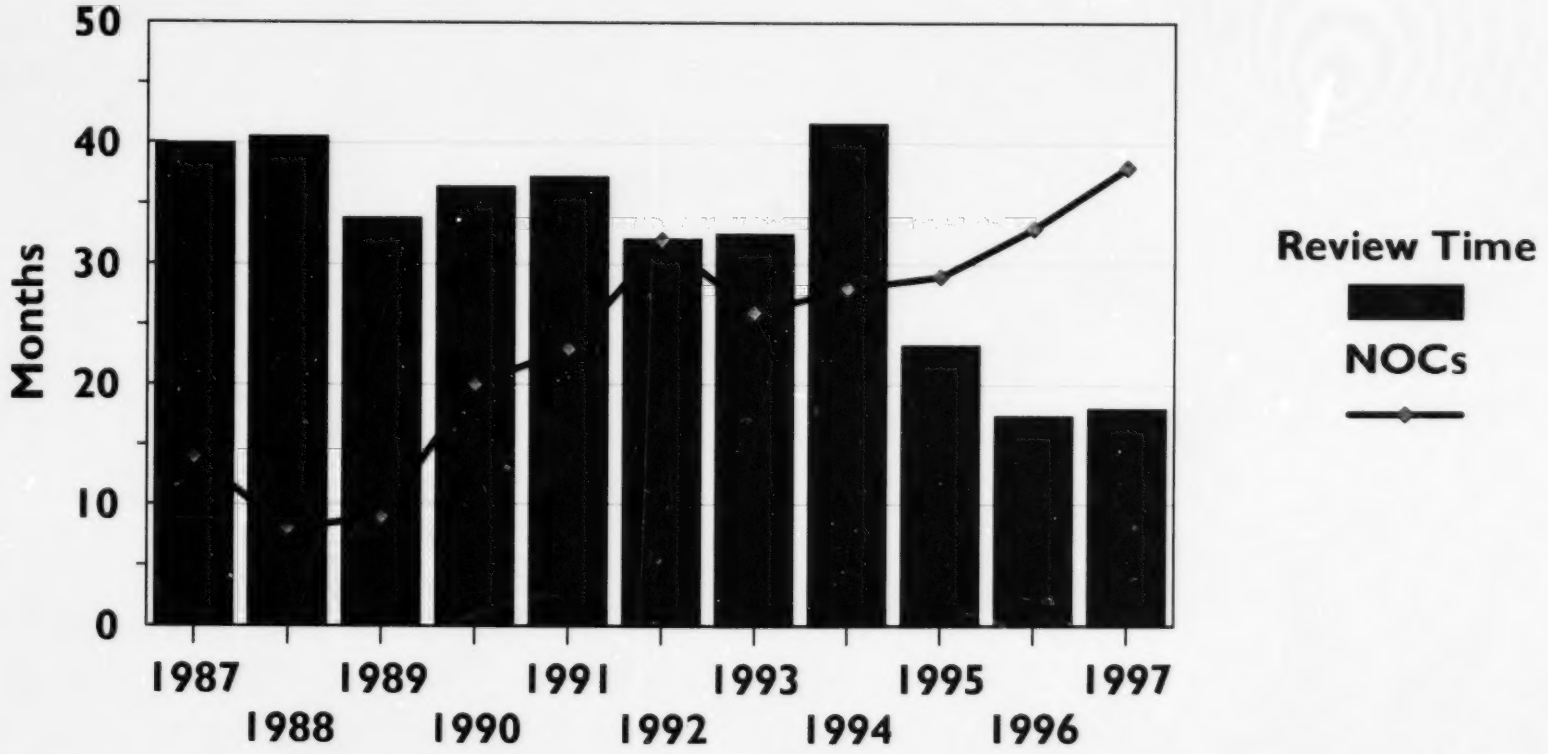
- Drug Submission Tracking System
- Review Status Reports as desired
- Quarterly Reports (public)
- Annual Reports (public)
- Individual Company Access to own submissions

Selected Performance Comparisons

- Purpose: to determine efficiency, to verify other agency's claims, to indicate improvements, to assist resource allocation.
- Possible Comparisons:
  - against previous performance
  - against targets
  - against international "peers"
- International Activity
  - initiated by TPP to benchmark against, verify
  - role of Centre for Medicines Research (UK)
- Issues:
  - standardization challenges:
    - measurement
    - processes
  - highlights performance

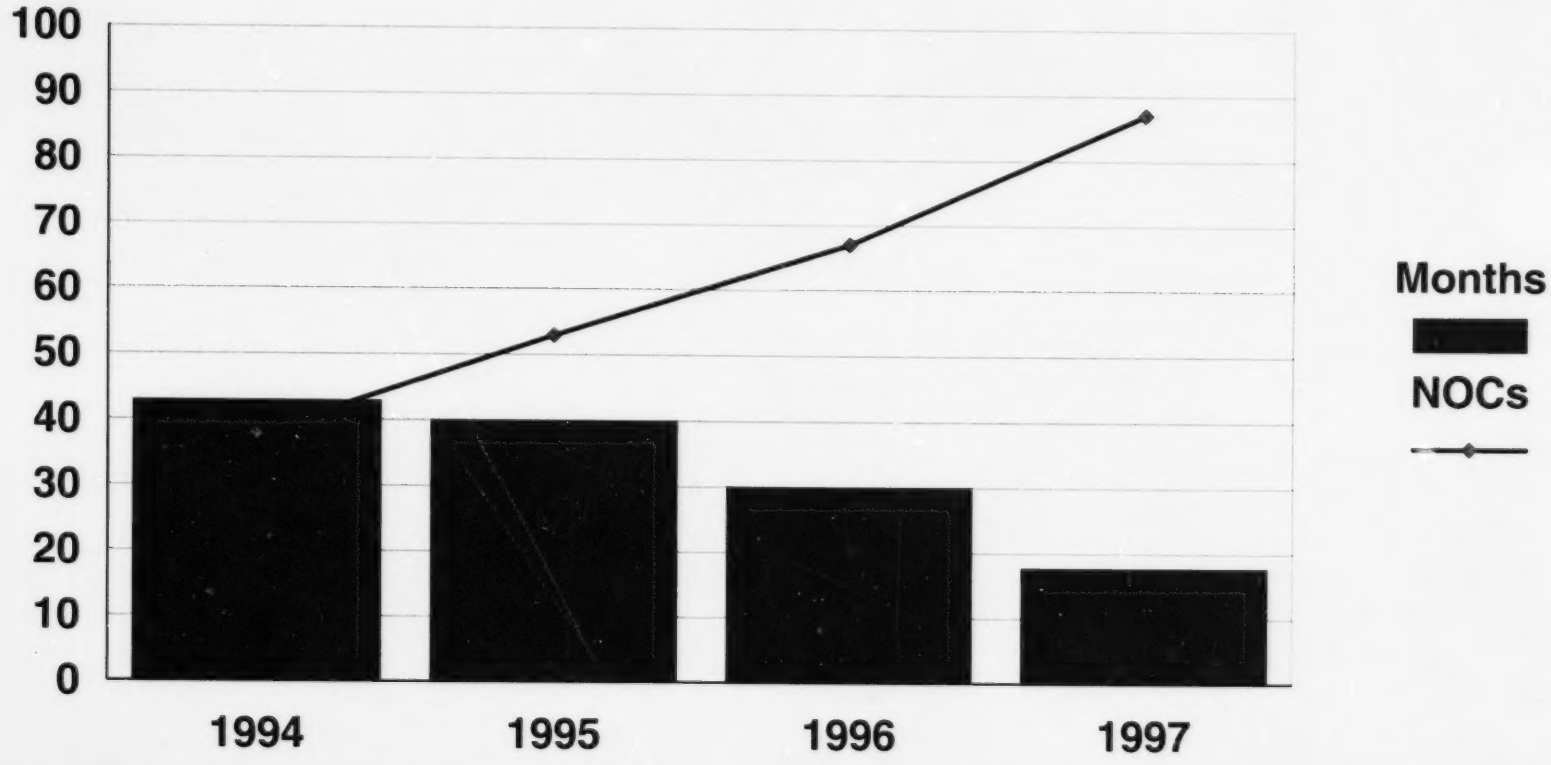
Submission Review Performance
New Active Substances

Average Review Time to Approval



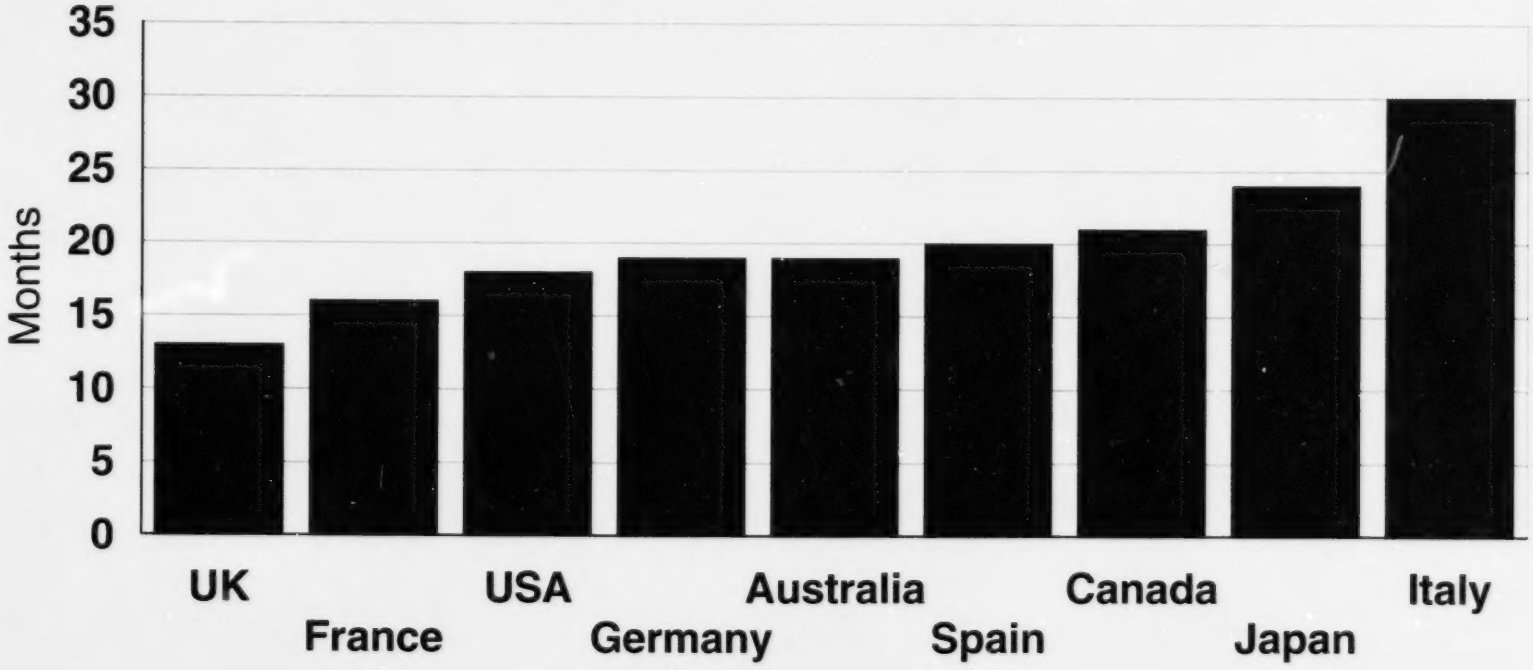
Submission Review Performance
Abbreviated New Drug Submissions

Average Review Time To Approval - 1997



International Review Comparisons
As Presented by PMAC to DM

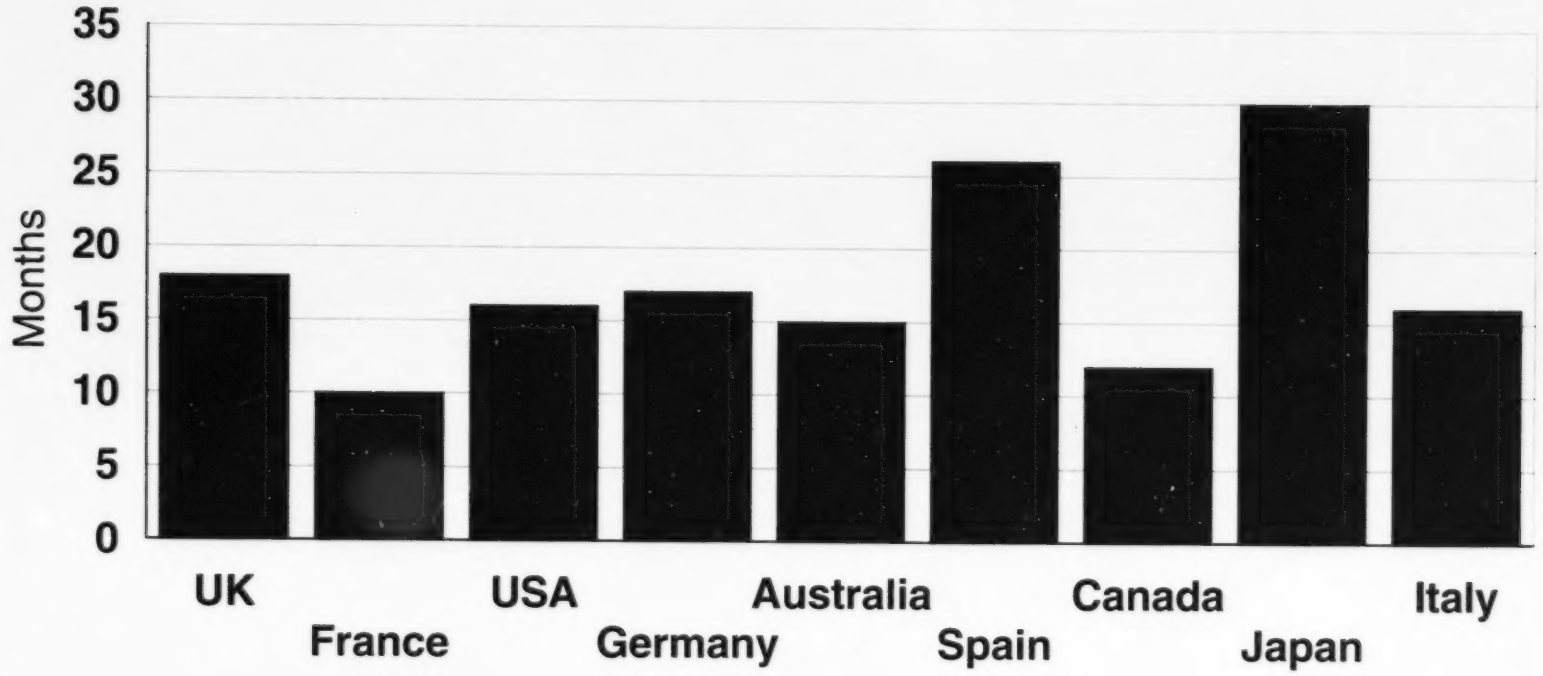
Median Review Time to Approval - 1995



Source: CMR Report

International Review Performance
Same Source; Another Perspective

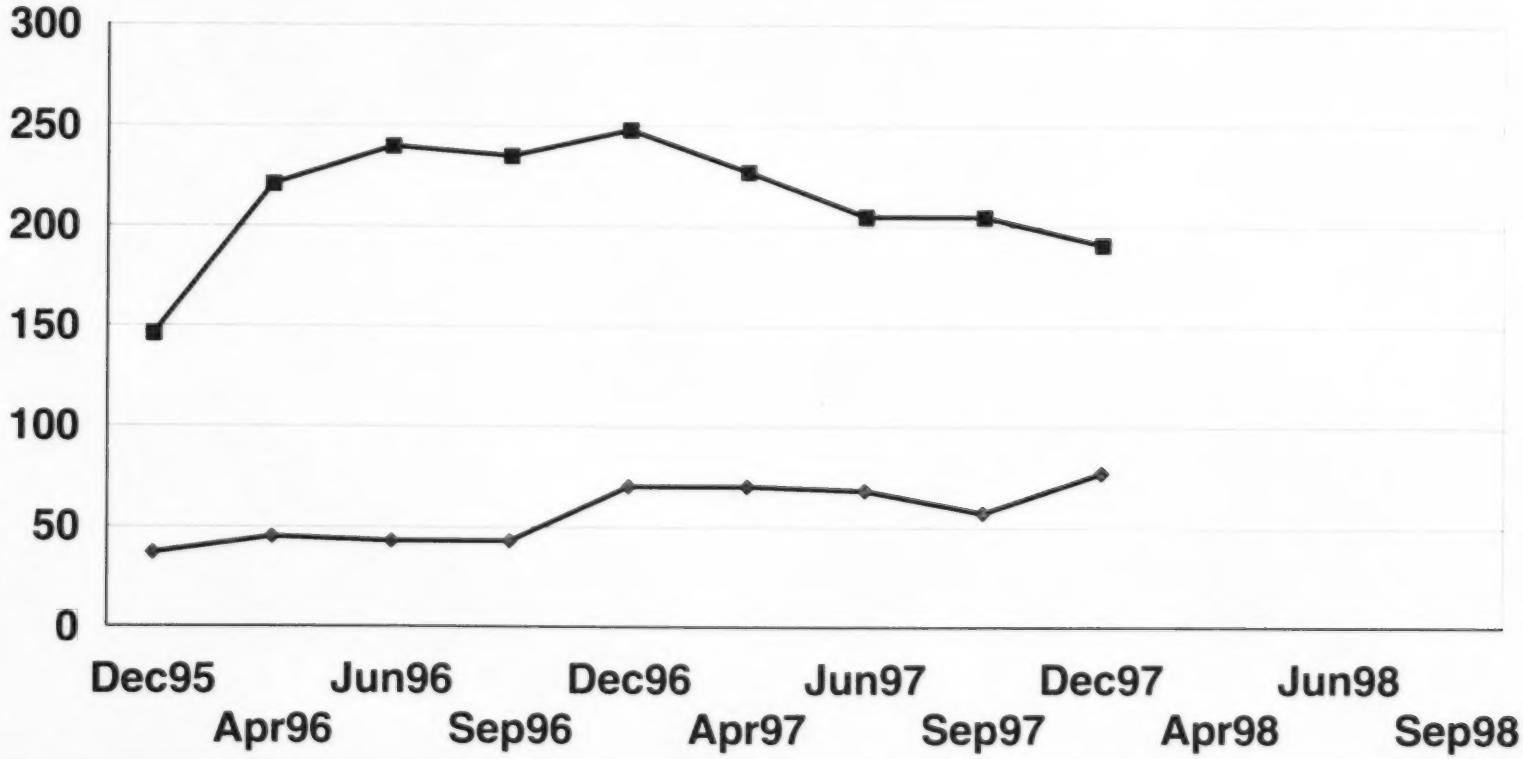
Average Review Time to Approval - 1996



Source: CMR Report

Submission Review Tracking
Useful Management Tool

Workload/backlog - NDSs/ANDSs



Singulaire
Review History

- ✓ Canada — 16 months
  - ✓ Screening — 42 days
  - ✓ Deficiency — 10 days
  - ✓ Screening — 1 day
  - ✓ Review:
    - ✓ Clinical — 191 days
    - ✓ Chem/Manuf. — 145 days
  - ✓ Holding — 270 days

✓ Could have been 8 months

4. Policy/Operational Initiatives
A Foundation of Policy & Science

1. **Policy/Regulation Development**
2. **Process/Operations Enhancement**
3. **International Partnerships**

Policy/Regulation Development Relevant to Pre-Market Review

- Product Licensing
- Clinical Trials Reform
- Special Access Programme
- Natural Health Products
- Blood Standards
- Tissues & Organs Standards
- Disinfectants/Sanitizers
- Rx to OTC Switches

Process/Operations Initiatives Relevant to Pre-Market Review

- ► Management of Drug Submissions Policy
- ► Policies/Guidelines - ICH and TPP
- ► New Organization Structure in BPA
- ► Expert Advisory Committees
- ► Desktop Reference Tools
- ► Electronic Templates
- ► Electronic Transmission of Information
- ★ Submission Review Process Re-Engineering
  - ★ Quality Improvement Initiative
  - ★ HIV/AIDS Working Group
- ★ Office of Continuing Education
  - ★ MRC/PMAC/TPP Research Fellowships

International Partnerships
Harmonization & Cooperation

- ► Standards - ICH (observer) & GHTF (co-chair)
- ► Other Initiatives (PER, PIC, APEC, CIOMS, WHO, +)
- ► MRA/MMRs on GMP Compliance/Medical Devices
  - ► European Union
  - ► Switzerland, EFTA,
  - ► Australia/New Zealand/Japan
  - ? USA
- ► MRAs on Pre-market Review
  - ► Shared/Joint Reviews

5. Consultation & Communications
A Wide Range of Stakeholders

- Industry
  - Innovative
  - Generic
  - OTC
  - NHP
  - Disinfectants
  - Medical Devices
- Academia
  - Deans of Pharmacy
  - Deans of Medicine
  - Deans of Nursing
- 3rd Party Payers
  - Provinces
  - Private
- Health Professions
  - Doctors
  - Pharmacists
  - Hospital Pharmacists
  - Hospitals
  - Complementary Practitioners
- Patient Advocacy Groups
  - Blood
  - HIV/AIDS
  - Heart & Stroke
  - Etc.
- Consumers

Consultation & Communications
A Recognized TPP Strength

- Strategic Planning & Ongoing
  - Advisory Committee on Management
  - Association Principals
  - Association Liaison Meetings
  - Staff Planning Workshops
- Special Issues
  - Consultation Workshops
    - Policy/Regulatory Reform
    - Cost Recovery
  - Expert Working Groups
    - Blood Standards
    - Tissues & Organs Standards
  - Advisory Panels
  - Advisory Panels
    - Natural Health Products
    - Functional Foods/Nutriceuticals
    - Electronic transmission of Information
  - Special Events
    - Consumer Blood Group
    - HIV/AIDS Workshop & Working Group

Increased Transparency/Participation Laudable Goals But....

- Efforts/Initiatives
  - Publication of Submission Dates
  - Product Monograph
  - Submission Review Report
  - Expert Advisory Committees
  - Dear Doctor/Pharmacist/Hospital Letters
  - Issue/Process Fact Sheets
- Challenges/Limitations
  - Consumers/Patient Advocates
  - Resources
  - Copyright
  - ATI - proprietary information

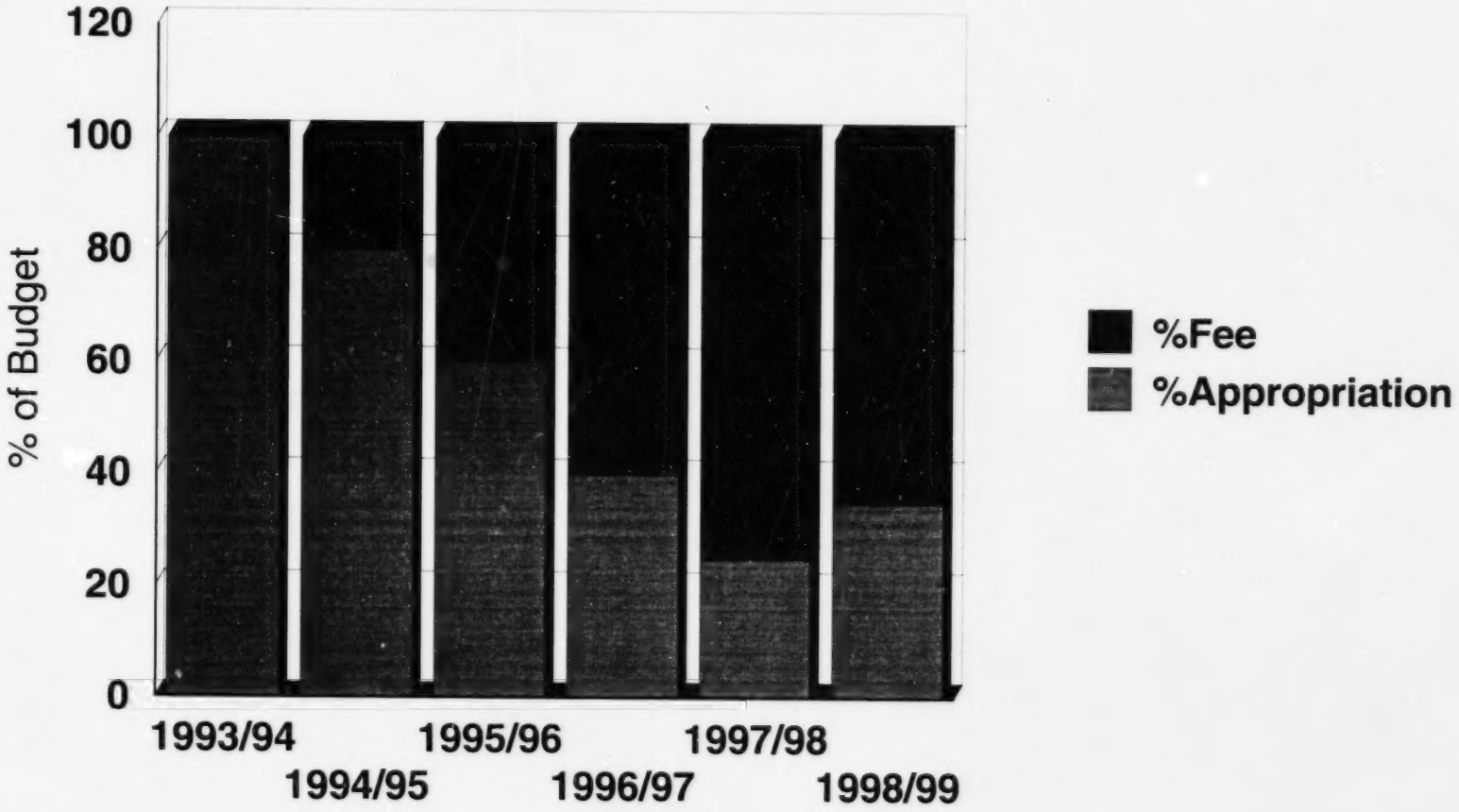
6. Cost Recovery Initiative
The Quest for Stabilized Funding

- Programme Review - Appropriations cut by 50%
- Cost Recovery Initiative
  - ✓ Drugs Phase I - Annual Product Fees
  - ✓ Drugs Phase II - Submission Review Fees
  - ✓ Drugs Phase III - Establishment Licensing Fees
  - ✓ Med. Devices Phase I - Part V Fees
  - ✓ Med. Devices Phase II - Product/Establishment
  - ★ Therapeutic Products - Phase IV - Evaluation
- Appropriations
  - ✓ New funds for Blood Regulation
  - ★ Continuing Erosion
- Considerations
  - Firewalls built between Review and Revenue
  - Only link between Workload and Wherewithal
  - ★ Health Canada commitments not being honoured

Health Canada Commitments
Ground Keeps Shifting

- ► Initial Cost Recovery assumption
  - 50% of TPP budget cut
  - to be replaced by fee revenue
  - cuts/taxes keep coming
- ► Appropriations for Ministerial Decisions not forthcoming
  - $2M to cover NHP exemptions
  - $5M to cover Med. Devices postponement
- ► Fee revenue ($6M) not returned to Programme
  - fees collected in 1997: work to be performed in 1998
- No resolution 6 months into fiscal year

Programme Funding
History of Shift in Sources



7. Barriers to the Enhanced Performance

Adjustments Needed - Expectations or Means?

- × Continuing Cuts to Budgets
  - ► Departmental "Taxes"
  - ► Questionable Commitments ($5M)
- × Inability to Retain Revenue
  - ► "Lapsed" Fee Revenue ($6M)
- × Inadequate/Inappropriate Departmental Services
  - ► Human Resources
    - ► Recruitment/Retention of Scientific Staff
    - ► Speed of Process
  - ► Finance/Administration
  - ► Information Technology
  - ► Accommodation
- × Departmental Mind-Set/Structure